

**CURRENT GOOD TISSUE PRACTICE FOR HUMAN CELL, TISSUE, AND
CELLULAR AND TISSUE-BASED PRODUCT ESTABLISHMENTS; INSPECTION
AND ENFORCEMENT**

FINAL RULE

Docket Number 97N-484P

References

1. U.S. Department of Health and Human Services, Center for Disease Control and Prevention, "Update: Allograft-Associated Bacterial Infections--United States," Morbidity and Mortality Weekly Report, vol. 51, no. 10, pp. 207-210, March 15, 2002.
2. Diringer, H. and H.R. Braig, "Infectivity of Unconventional Viruses in Dura Mater," Lancet, pp. 439-440, 1989.
3. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, "Class II Special Controls Guidance Document: Human Dura Mater; Draft Guidance for Industry and FDA," October 2002.
4. U.S. Department of Health and Human Services, Food and Drug Administration, Transmissible Spongiform Encephalopathies Advisory Committee Meeting Transcript, pp. 1-100, June 26, 2002.
5. Wilhelmus, K. R., R. D. Stulting, J. Sugar, and M. M. Khan,

1997N-0484P

50 P2

"Primary Corneal Graft Failure," Archives of Ophthalmology, vol. 113, pp. 1497-1502, December 1995.

6. Remeijer, L., P. Doornenbal, A. J. M. Geerards, W. A. Rijneveld, and W. H. Beekhuis, "Newly Acquired Herpes Simplex Virus Keratitis After Penetrating Keratoplasty," Ophthalmology, vol. 104, No. 4, pp. 648-652, April 1997.

7. Health Care Utilization Project (HCUP), Nationwide Inpatient Sample (NIS) for 2000, Outcomes for Principle Procedure 13, Corneal transplant, Available online at <http://www.hcup-us.ahrq.gov/nisoverview.jsp>.

8. Health Care Financing Review, 2000 Statistical Supplement, Submitted Charges per Person Served, Calendar Year 1998, U.S. Department of Health and Human Services, Center for Medicare and Medicaid Services, Table 59, pp. 226-227.

9. Lord, C. F., M. C. Gebhardt, W. W. Tomford, and H. J. Mankin, "Infection in Bone Allograft: Incidence, Nature and Treatment," The Journal of Bone and Joint Surgery, vol. 70-A, No. 3, pp. 369-376, March 1988.

10. Hardin, C. K., "Banked Bone," Otolaryngologic Clinics of North America, vol. 27, No. 5, pp. 911-925, October 1994.

11. Detailed Diagnoses and Procedures Data, National Hospital Discharge Survey 2000, Series 13, No. 153, Table 46, p. 153, November 2002.

12. Abecassis, M. M., "Transmission of Cytomegalovirus by Skin Allograft," Tissue and Cell Report, vol. 2, No. 1, pp. 14-17, 1995.

13. Gala, J., A. Vandenbroucke, B. Vandercam, J. Pirnay, N. Delferriere, and G. Burronboy, "Human Immunodeficiency Virus in Fresh or Cryopreserved Postmortem Skin: Potential Implications for Skin Handling and Allografting," Journal of Clinical Pathology, vol. 50, pp. 481-484, 1997.

14. Kuehnert, M. J., E. Clark, S. R. Lockhart, D. R. Soll, J. Chia, and W. R. Jarvis, "Candida Albicans Endocarditis Associated with a Contaminated Aortic Valve Allograft: Implications for Regulation of Allograft Processing," Clinical Infectious Diseases, vol. 27, pp. 688-91, October 1998.

15. Webb, I. J., F. S. Coral, J. W. Andersen, A. D. Elias, R. W. Finberg, L. M. Nadler, J. Ritz, and K. C. Anderson, "Sources and Sequelae of Bacterial Contamination of Hematopoietic Stem Cell Components: Implications for the Safety of Hematotherapy and

Graft Engineering," Transfusion, vol. 36, pp. 782-788, 1996.

16. Price, K. J., P. F. Thall, S. K. Kish, V. R. Shannon, and B. S. Andersson, "Prognostic Indicators for Blood and Marrow Transplant Patients Admitted to an Intensive Care Unit," American Journal of Respiratory Critical Care Medicine, vol. 158, pp. 876-884, 1998.

17. Espinosa, M. T. F., R. Fox, R. J. Creger, and H. M. Lazarus, "Microbiologic Contamination of Peripheral Blood Progenitor Cells Collected for Hematopoietic Cell Transplantation," Transfusion, vol. 36, pp. 789-793, 1996.

18. Kogler, G., J. Callejas, P. Hakenberg, J. Enczmann, O. Adams, W. Daubener, C. Krempe, U. Gobel, T. Somville, and P. Wernet, "Hematopoietic Transplant Potential of Unrelated Cord Blood: Critical Issues," Journal of Hematotherapy, vol. 5, pp. 105-116, 1996.

19. Prottas, Jeffrey, "A Study of the Tissue Procurement and Distribution System of the United States," Brandeis University, FDA/HRSA Contract No. 240-090-0048, October 1995.

20. American Medical Association, Center for Health Policy Research, Physician Socioeconomic Statistics, 2002 Edition, Table

41, p. 83, 2002.

21. North American Industry Classification System (NAICS), available online at <http://www.naics.com>.

22. U.S. Small Business Administration, Office of Size Standards, Table of Size Standards, Sector 62, Health Care and Social Assistance, 2002.

23. HCUP, NIS for 2000, Outcomes for Principle Procedure 157, Amputation of Lower Extremity, available online at <http://www.hcup-us.ahrq.gov/nisoverview.jsp>.

24. AHRQ, HCUP, NIS for 2000, Outcomes for Principle Procedure 43, Heart Valve Procedures, available online at <http://www.hcup-us.ahrq.gov/nisoverview.jsp>.

25. "Blood Collection and Transfusion in the United States in 1997," Transfusion, vol. 42, pp. 1253-1300, 2002.

26. AHRQ, HCUP, NIS for 2000, Outcomes for Principle Procedure 3, Bacterial Infection, Unspecified Site, available online at <http://www.hcup-us.ahrq.gov/nisoverview.jsp>.

27. U.S. Department of Labor, Bureau of Labor Statistics,

Available online at <http://www.bls.gov/cpi>.

28. AHRQ, HCUP, NIS for 2001, Outcomes for Principle Procedure 142, Partial Excision of Bone, available online at <http://www.hcup-us.ahrq.gov/nisoverview.jsp>.

29. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, American Society for Reproductive Medicine and RESOLVE, 1999 Assisted Reproductive Technology Success Rates: National Summary and Fertility Clinic Reports, 2000.

30. Fee Schedule 1/98, Donor Semen 0.5cc and Donor Semen 0.8cc-1.0cc, The Sperm Bank of California, at <http://www.thespermbankofca.org/fees.html>

31. Hogan, R. N., P. Brown, and E. Heck, "Risk of Prion Disease Transmission From Ocular Donor Tissue Transplantation," Cornea, vol. 18, No. 1, 1999, pp. 2-11.

32. U.S. Department of Labor, Bureau of Labor Statistics, "Employer Costs for Employee Compensation per hour worked for Civilian Workers in Private Industry and State and local Governments, March 2003, available online at <http://www.bls.gov>.

33. International Conference on Harmonisation; Guideline on Clinical Safety Data Management: Definitions and Standards for Expedited Reporting; Availability (60 FR 11284, March 1, 1995)

34. FDA Compliance Guide - Chapter 1- General: Sec. 130.300 FDA Access to Results of Quality Assurance Program Audits and Inspections.

35. Draft "Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing - Current Good Manufacturing Practice" dated August 2003.

36. "Proposed Approach to Regulation of Cellular and Tissue-Based Products" meeting transcript dated March 17, 1997.

37. Reinventing the Regulation of Human Tissue - 1997

38. Approach to the Regulation of Human Tissue - 1997

39. 2000-2001 Comprehensive Accreditation Manual for Pathology and Clinical Laboratory Services: pp. QC 36 and 37.

40. Compliance Program 7341.002 - Inspection of Tissue Establishments.

41. 2001 Eye Banking Statistical Report

42. General Principles of Software Validation; Final Guidance for Industry and FDA Staff dated January 11, 2002.

43. Sullivan MT, J McCullough, GB Schreiber, EL Wallace, "Blood collection and transfusion in the United States in 1997," *Transfusion*, 2002;42:1253-1260.

44. ISO 9000:2000, International Standard, Quality management systems-Fundamentals and vocabulary, pp. 10, 15-16.

45. Barker, JN, JE Wagner, "Umbilical cord blood transplantation: current state of the art," *Current Opinion in Oncology*, March 2002; vol. 14(2): pp. 160-164.